

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION**

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| THOMAS A. SIMONIAN, |] | |
| |] | |
| Plaintiff, |] | 10 C 1202 |
| v. |] | |
| |] | Judge James F. Holderman |
| CIBA VISION CORPORATION, |] | |
| |] | |
| Defendant. |] | |

Relator's Response to The Novartis Defendants' Motion To Dismiss

Thomas A. Simonian, as *qui tam* relator ("Relator"), respectfully submits this Response to the motion to dismiss filed by the Novartis Defendants (Novartis Consumer Health, Inc. ("NCH"); Novartis Animal Health, Inc.; Novartis Pharmaceuticals Corp.; and Ciba Vision Corporation). The Novartis Defendants argue that the cases against them should be dismissed because Section 292(b) of the Patent Act is unconstitutional (for two reasons), and the case should be dismissed against NCH because of a prior pending (by a few hours) action. As set out below, the Novartis Defendants' motion should be denied.

I. Introduction and Summary of Argument

In the face of the amended complaints filed in this case, the Novartis Defendants (hereafter "Novartis") have not moved to dismiss based on any pleading issues. Instead, Novartis contends that the statute pursuant to which they have been sued is unconstitutional, on two separate grounds. First, Novartis argues that Section 292(b) violates the "Take Care" clause of Article II, because the executive branch does not have "sufficient control" of *qui tam* litigation like this case. Second, Novartis argues that Section 292(b) also violates the "Appointments" clause of Article II, because the relator is somehow serving as an officer of the United States.

As shown below, the Judges who addressed the issue found that (a) the executive branch

has sufficient control of false marking *qui tam* cases such that the “Take Care” clause has not been violated, and (b) that the relator has not been appointed an “officer of the United States,” and thus the “Appointments” clause has not been violated either. As Novartis apprised the Court, Judge Brinkema rejected the “Take Care” clause argument in *Pequignot v. Solo Cup*, after receiving briefing from the parties and the United States, which had intervened to defend the statute’s constitutionality. Remarkably, Novartis failed to apprise the Court that Judge Whitney rejected both the “Take Care” clause and “Appointments” clause arguments in *Harrington v. Ciba Vision Corporation*, after receiving briefing from the parties – including current defendant Ciba Vision – and the United States, which once again intervened to defend the statute’s constitutionality. And, most recently, Judge Anderson likewise rejected both arguments in *Shizzle Pop v. Wham-O*. No false marking case has held to the contrary.

Finally, with regard to Novartis Consumer Health’s argument based on a “prior pending case,” Mr. Simonian and the Public Patent Foundation – the two relators who independently filed on the same day, within hours of each other, a *qui tam* suit against NCH for falsely marking its Prevacid product with an expired patent – have reached an agreement to consolidate their cases into one, here in the Northern District of Illinois. The result is that: (a) this Court need not address NCH’s standing argument; (b) the Southern District of New York need not address the very same constitutional argument in that case as has been raised by NCH in this case; and (c) the parties can focus on the merits of the Prevacid false marking claim, rather than the question of who beat the clock.

II. Brief Factual Summary

A. Overview of the Four Pending Novartis Complaints

Novartis Consumer Health “Prevacid” Amended Complaint¹

There has never been a time when Novartis’ over-the-counter Prevacid product was patented. Nonetheless, on the day it was released for public sale, Novartis marked Prevacid with an expired patent (the ‘098 patent). (Complaint, ¶4). At the time it did so, Novartis was aware that the patent had expired; indeed, it had previously been involved in litigation concerning this patent, in which the expiration date was an issue. (*Id.*, ¶43). The Relator alleges that the false marking caused injury to the public, was intended to deceive the public, and was part of an overall strategy to falsely mark patents on Novartis’ products in order to secure or protect market share and confuse consumers. (*See e.g., id.* at ¶¶8, 10, 31-33, 46-55).

Novartis Pharmaceuticals Corp. “Hypo Tears” Amended Complaint

The Relator alleges that Novartis has falsely marked the expired ‘205 patent – which expired in 2001 – on its Hypo Tears eye-drop product. Unlike with Prevacid, this product may have been at one time properly marked with the ‘205 patent before it expired. But as of the filing of the amended complaint, more than a year after the patent expired, one can see it marked on the item for sale on Walgreens’ store shelves. (Complaint, ¶19).

Novartis Animal Health US, Inc. “Interceptor” Amended Complaint

The Relator alleges that Novartis has falsely marked the expired ‘520 patent – which expired in 2005 – on its Interceptor Flavor Tabs branded products. Unlike with Prevacid, this

¹ All four amended complaints are attached to “Relator’s Response to The Novartis Defendants’ Motion For a Finding of Relatedness, For Reassignment of Higher-Numbered Cases, and To Stay” (Docket #23 in case no. 10 C 1202).

product may have been at one time properly marked with the '520 patent before it expired. But, as shown in the amended complaint, the product is sold with the patent marked on the packaging and the marking can be found on the company's website. (Complaint, ¶¶20-23).

Ciba Vision Corporation "Clear Care" Amended Complaint

In similar fashion, the Relator alleges that Novartis' Ciba Vision unit has falsely marked the expired '689 patent on its Clear Care product. Unlike with Prevacid, this product was at one time properly marked with the '689 patent before it expired. But as of the filing of the amended complaint, more than a year after the patent expired, one can see it marked on the product on Ciba Vision's website and can see it marked on the item for sale on Walgreens' store shelves. (Complaint, ¶22).

B. Overview of the United States's Involvement in False Marking Cases

1. The Novartis Cases

As required by Local Rule 3.4, the Relator filed in each of the cases a "Notice of Claims Involving Patents," (*see, e.g.*, NCH (Prevacid) Notice, **Exhibit A** hereto), [i]n order to assist the clerk in complying with the requirement to notify the commissioner" of the PTO pursuant to 35 U.S.C. §290. *See, e.g.*, §290 Notice re: NCH (**Exhibit B** hereto).

Novartis filed its motion challenging the constitutionality of Section 292(b), and provided the required Notice to the Attorney General. This Court certified to the Attorney General the fact that Novartis has drawn in to question the constitutionality of Section 292(b), granted the United States until November 8, 2010 "to advise the court whether it wishes to intervene for any purpose," and mailed a copy of the Order to the Attorney General. *See, e.g.*, NCH Order of 9/20/10 and NCH Minute Entry of 9/22/10 re Mailing (**Group Exhibit C** hereto).

2. Other False Marking Cases

The United States has intervened in at least four false marking cases. As the Court is aware, the United States intervened and prevailed in *Pequignot v. Solo Cup*. As the Court is also aware, the United States intervened in *Stauffer*, where, *inter alia*, the Federal Circuit confirmed the United States' right to intervene on the merits. 2010 WL 3397419, *7 (Fed. Cir. August 31, 2010) ("We agree with the government that the district court made an error of law in denying the government's motion to intervene under Rule 24(a)(2)"). The United States also intervened in *Harrington v. Ciba Vision* (see Briefs attached as **Exhibit D** and **E** hereto), and prevailed there as well. See Transcript of Argument and Ruling, **Exhibit F** hereto. Recently, the United States intervened in *Hy Cite Corporation v. Regal Ware, Inc.*, once again defending 292(b) from attack on Article II grounds. (**Exhibit G** hereto).

III. **Argument**

A. **The *Qui Tam* Mechanism in Section 292 Does Not Facially Violate Constitutional Separation of Powers Principles**

In the United States' briefs, the government has explained at length why Section 292(b)'s mechanism to use *qui tam* relators to help enforce the false marking provision of Section 292 is constitutional. See, Exh. D, pp. 11-28, Exh. E, pp. 3-11, and Exh. G, pp. 16 - 32. Accordingly, the relator will not belabor the point by pretending that he can better state the government's arguments for it. By way of brief summary, Section 292(b)'s constitutionality is supported by the longstanding history of such *qui tam* provisions, the role of the relator relative to the role of the government (*i.e.*, the relator is not an appointed officer of the government, but rather a person who incidentally furthers the government's interests in enforcing the statute while he is pursuing his own financial interests), the government's own power and ability to enforce Section 292, and

the mechanisms in place to allow the government notice and a meaningful opportunity to be heard in every false marking case. At bottom, the fact that Congress empowered and encouraged citizens to assist the government (rather than replace the government) in curtailing false marking, does not violate the Executive's duty to "take Care that the Laws be faithfully executed." As the United States recently argued: "Congress's decision to provide more than one mechanism of enforcement does not impinge on any function that the Constitution requires the Executive Branch exclusively to perform." (Exh. G, p. 24).

Every court to date has rejected the argument that Section 292 violates Article II's Take Care clause. *Solo Cup*, 640 F.Supp.2d 714, 724-8 (E.D. Va. 2009); *Shizzle Pop, LLC v. Wham-O, Inc.*, 10 CV 03491 (C.D. Cal. August 2, 2010) (**Exhibit H** hereto, p. 4); *Zojo Solutions, Inc. v. Stanley Works*, 2010 WL 1912650, *2 (N.D.Ill. May 12, 2010) (**Exhibit I** hereto); *Ciba Vision*, Exh. F, pp. 117 - 120. Novartis mentions (and tries to distinguish) only one of these cases, *Solo Cup*, "justifying" its decision to ignore the others – including one in which defendant Ciba Vision itself fully litigated the issue – on the purported grounds that *Solo Cup* is "the only reported decision rejecting an Article II challenge to §292." (Novartis Brief at 9). The qualifier "reported" doesn't make a lick of difference, and doesn't absolve Novartis of its failure to apprise the Court of relevant case law.²

As shown below, Judge Brinkema, Judge Whitney, and Judge Anderson correctly held

²If anything, the qualifier makes things worse for Novartis. Had Novartis stated that *Solo Cup* was "the only decision," perhaps its failure to cite the *Ciba Vision* case could somehow be explained by a loss of memory. The qualifier ("reported"), however, indicates that Novartis was in fact well aware of the *Ciba Vision* opinion (and perhaps the *Wham-O* opinion as well), and hoped to craft a mechanism to avoid sharing Judge Whitney's ruling and thought process with this Court.

that Section 292(b) does not violate the “Take Care” clause of Article II. Novartis’ arguments to the contrary should be rejected, for the reasons set out in those courts’ opinions and in the United States’ briefs.

1. Judge Brinkema’s Opinion in *Solo Cup*

In *Solo Cup*, Judge Brinkema rejected on three grounds the argument that Section 292(b) violates constitutional separation of powers principles. First, “like Justices Souter and Stevens [in *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765, 800 (2000)] and the Fifth Circuit [in *Riley v. St. Luke’s Episcopal Hospital*, 252 F.3d 749, 752 (5th Cir. 2001)(*en banc*)], the Court finds the long history of *qui tam* statutes, including many passed by the First Congress soon after the signing of the Constitution ... highly persuasive as to their Constitutionality.” 640 F.Supp.2d at 726. Second, there are sufficient controls such that the Executive Branch has “the ability to assert its interests in a §292(b) *qui tam* action.” *Id.* at 727. In so finding, Judge Brinkema rejected the argument that the more stringent controls of *Morrison v. Olson* (487 U.S. 654 (1988)) were required in a false marking case, given the differences in the power and role of the relator in a civil false marking case on the one hand and the power and role of the independent prosecutor in *Morrison* – who had the power to initiate criminal prosecutions – on the other. *Id.* In a false marking *qui tam* case, which Judge Brinkema found was civil in form,³ the United States has sufficient control because it has a right to notice of the action (under 35 U.S.C. §290), the United States has a right to intervene under Rule 24(a)(2),⁴

³The Federal Circuit affirmed this point in *Pequignot v. Solo Cup*, 608 F.3d 1356, 1363 (Fed. Cir. 2010) (“A *qui tam* action is civil in form even though it arises under a criminal statute”).

⁴The Federal Circuit affirmed this point in *Stauffer*, 2010 WL 3397419, *7.

the United States has the right to prevent dismissal without its consent, and the United States has the right to prevent a relator's interference (pursuant to Fed.R.Civ.P. 26(c)) with an ongoing investigation or prosecution. *Solo Cup*, 640 F.Supp.2d at 727. Third, Judge Brinkema found that some of Solo Cup's arguments were speculative in nature, and would not use a speculative argument to find the statute unconstitutional. *Id.* at 728.

2. Judge Anderson's Opinion in *Wham-O*

In *Wham-O*, Judge Anderson found Judge Brinkema's analysis "persuasive" and "decline[d] to hold that 35 U.S.C. §292(b) is unconstitutional." (Exh. H, p. 4). In particular, Judge Anderson referenced both the "minor intrusion into the power of the Executive Branch since it authorizes the qui tam relator to bring only one type of civil suit at his own expense"⁵ and that "the Executive Branch has the ability to assert its interests through procedures available under the Federal Rules of Civil Procedure." (*Id.*)

3. Judge Shadur's Opinion in *Stanley Works*

In *Stanley Works*, the defendant moved to dismiss for lack of subject matter jurisdiction because the relator could not properly bring suit consistent with Article II. Judge Shadur noted that if the Federal Circuit found a subject matter jurisdictional problem with Section 292 *qui tam* claims, "it would have been obligated to raise and address the issue *sua sponte*" in its false marking opinions. 2010 WL 1912650, * 2. Instead of doing so, the Federal Circuit emphatically

⁵By way of comparison, the members of the Public Company Accounting Oversight Board are "Officers of the United States," "exercise significant authority pursuant to the laws of the United States," and were given "expansive powers to govern an entire industry" – including the prescription and implementation of rules punishable by up to 20 years' imprisonment. *Free Enterprise Fund v. Public Company Accounting Oversight Board*, 130 S.Ct. 3138, 3147-48 (2010) (cited by Novartis).

confirmed Congress's intent to create a "cottage industry" of false marking bounty hunters in *The Forest Group, Inc. v. Bon Tool Co.*, 590 F.3d 1295, 1303-04 (Fed. Cir. 2010). Judge Shadur reasoned accordingly that the Federal Circuit had not found a subject matter jurisdictional problem with citizen relators' false marking suits. 2010 WL 1912650, * 2. And, in the event this was an oversight, Judge Shadur left the issue for the Federal Circuit to address if the action resulted in an appeal. *Id.*.

4. Judge Whitney's Opinion in *Ciba Vision*

After briefing by the parties and the United States, and after hearing lengthy argument, Judge Whitney held that Section 292(b) did not violate Article II. In so doing, Judge Whitney by and large agreed with Judge Brinkema's reasoning and logic. (Exh. F, p. 117; "the Court largely accepts Judge Brinkema's analysis regarding the Take Care Clause of the Constitution"). And where Judge Whitney disagreed, he did so in a way that is very unhelpful to Novartis. In this regard, Judge Whitney ruled that while he agreed that Section 292(b) was civil in nature, the Supreme Court's "sufficient control" test from *Morrison* should nonetheless apply (*id.*, p. 118) – as Novartis has argued here in their attempt to overcome *Solo Cup* (Novartis Brief at 10). When he applied the *Morrison* test, however, Judge Whitney found that Section 292(b) *still* passed constitutional muster:

Having reviewed the *Morrison* standard and the circuit court case law applying it to the False Claims Act, the Court now holds that the United States government, as an intervenor in this case, has demonstrated that the Executive retains sufficient control over a false marking case to ensure that the laws are faithfully executed.

The Court references the government's broad right to be heard in any case in which it has an interest pursuant to 28 U.S.C., Sections 517 and 518, as well as the government's right to intervene as an interested party under the Federal Rules of Civil Procedure.

It is the government's notice of a false marking action that has given the

Court the most pause. But the Court believes that the notice procedure for all patent cases, as well as the government's notification by receipt of the funds after the lawsuit, and its legal options for setting aside any previously obtained judgment, are sufficient to pass constitutional muster.

Exh. F, pp. 119-20.

5. Novartis' Arguments Should Be Rejected Again

As noted above, Novartis pretends that it only needs to surmount Judge Brinkema's opinion – a lone voice in the wilderness – in order to prevail. Thus, Novartis argues that Judge Brinkema got it wrong when she found that the *Morrison* test did not apply. But as Novartis learned first-hand in *Ciba Vision*, even under the *Morrison* test, there is “sufficient control” by the Executive Branch to “pass constitutional muster.” Acknowledging this *sub silentio*, Novartis contends that Rule 24's intervention rights are not enough to provide such control because, as a practical matter, there are too many false marking cases for the government to track. This argument should be rejected for at least two reasons. First, it is speculative, and a speculative argument about what might happen in other false marking cases – where the government supposedly might not be paying attention – cannot render Section 292(b) unconstitutional when applied to the facts of *this* case, where the government clearly *is* paying attention.⁶ *Solo Cup*, 640 F.Supp.2d at 728 (“It is unnecessary to decide whether, on different facts, Article II might be violated”). Second, Novartis' argument is defeated by Judge Whitney's point that the government receives “notification by receipt of the funds after the lawsuit” and has legal options “to set aside any previously obtained judgment.” (Exh. F, pp. 119-20). Thus, the government

⁶As Mr. Simonian's counsel has repeatedly advised the Court and Novartis, the government (through John Fargo, U.S. Department of Justice) has in fact been apprised of the case on an ongoing basis. Moreover, the Court has given the Attorney General clear notice and the opportunity to intervene and be heard in this case.

need not simultaneously micro-manage 400 false marking cases; instead the government can weigh-in where and when desired in an ongoing case (as in *Stauffer*), or await resolution of a pending case and address it at that time.

Finally, Novartis tries to give the false impression that unless Section 292(b) contains all the “control” features of the False Claims Act, then Article II is violated. The fact that False Claims Act cases have significant controls and do not violate separation of powers principles does not mean that the exact same controls are required in all *qui tam* cases. No case so requires, and, in fact, three cases hold to the contrary: the controls noted by Judge Brinkema – and the additional controls noted by Judge Whitney – are sufficient.

B. Section 292(b) Does Not Violate the Appointments Clause

Judges Whitney and Anderson reached the same conclusion: Section 292(b) does not violate the Appointments Clause “because it does not appoint an officer of the United States.” *Ciba Vision*, Exh. F, p. 120; *Wham-O*, Exh. H, p. 3 (“The Ninth Circuit has concluded that a *qui tam* relator, ‘who litigates only a single case,’ ‘receives no federal salary, and serves no specified term,’ does not exercise enough authority to be considered an officer who must be appointed by the President. As such, 35 U.S.C. §292(b) does not violate the Appointments Clause.”) (citation omitted).⁷ Judge Whitney explained his conclusion as follows:

As the Supreme Court has stated [in *United States v. Germaine*], the term “‘officer of the United States,’ embraces the ideas of tenure, duration, emolument and duties that are permanent, not occasional or temporary.” In contrast, a *qui tam* plaintiff is more akin to an agent, or as the Supreme Court stated in *Vermont Agency*, “an ‘assignee’ receiving a partial assignment of the government’s

⁷Judge Brinkema, while not addressing the Appointments Clause question head on, likewise noted that a Section 292(b) relator “can maintain only one type of suit – and action for false patent marking – and must do so at his own expense.” 640 F.Supp.2d at 727.

damages claim.” Therefore, 35 U.S.C. §292(b) does not violate the Appointments Clause.

Exh. F, p. 120 (citations omitted).

Novartis argues that the Supreme Court’s opinion in *Buckley v. Valeo* teaches to the contrary. As the United States recently explained in its *Regal Ware* brief, *Buckley* – which defines “officers” as “appointed officials” (424 U.S. at 131) – does not undermine the Supreme Court’s ruling in *Germaine*. Rather:

the opinion in *Buckley* means that, because the members of the Federal Elections Commission served in federal offices and conducted executive functions, they had to be appointed pursuant to the Appointments Clause. That is quite different from requiring private persons who sue for themselves and simultaneously provide a benefit for the United States to be Officers of the United States in office under the Appointments Clause.

Exh. G, p. 35. Indeed, by way of contrast, in *Free Enterprise Fund*, the Supreme Court addressed an Article II issue where in fact executive power had been delegated to “Officers of the United States,” as all parties conceded. 130 S.Ct. at 3148. Those individuals, members of a “Government-created, Government-appointed entity, with expansive powers to govern an entire industry,” were appointed to 5-year terms, received salaries, and could only be removed from office for cause. *Id.* at 3149. Those are the indicia of an “officer” who is subject to the Appointments Clause, as Judge Anderson found. *Wham-O*, Exh. H, p. 3.

In sum, Section 292(b) does not violate the Appointments Clause. Novartis’ motion to dismiss on this ground should be denied.

C. Because Simonian and the Public Patent Foundation Have Agreed to Pursue One Recovery in One Case Against NCH, NCH’s Motion to Dismiss Should Be Denied

NCH’s recent suggestion that Simonian and the Public Patent Foundation (“Foundation”)

plan to proceed in two separate cases against NCH is false. As set out in the attached letter from Professor Ravicher, it is the Foundation's and Mr. Simonian's intent that NCH only defend one false marking case, and do so in the Northern District of Illinois:

It is our and your intent that the two Prevacid cases against NCH be consolidated into one so that: (a) NCH faces only one potential adverse judgment; (b) the United States will receive 50% of only one recovery; and (c) the relator (here a combination of your client, Mr. Simonian, and the Public Patent Foundation) will share the other 50% of only one recovery. Given our agreement, there is no dispute between the plaintiff-relators, and thus we respectfully submit that the Court need not reach the "first-filed" issue raised by NCH, as we intend to moot that issue.

Letter of September 27, 2010, **Exhibit J** hereto.

Given Judge McMahon's misapprehension about the Foundation's intent (her handwritten note indicates that NCH convinced her that the Foundation intended to have two cases proceed against NCH), that court is not currently inclined to transfer the New York NCH case, but rather awaits Your Honor's decision. Accordingly, rather than transfer and consolidate, it may make more sense – with this Court's permission, which we respectfully request – for the Foundation's counsel to move for admission *pro hac vice* in the NCH case pending here, have Mr. Simonian move to substitute the Foundation as relator in this NCH case, and then have the case here proceed apace – in which case, the Foundation would voluntarily dismiss the New York case pending before Judge McMahon.

In any event, two things are readily apparent. First, it makes no sense for two courts to address Novartis' constitutional arguments (thus requiring the government to intervene in two cases) and supervise discovery concerning NCH's false marking of Prevacid. In this regard, Mr. Simonian has alleged in these four consolidated cases that Novartis has an overall strategy of false marking, and thus even if this Court were to dismiss Mr. Simonian's NCH case, he would

seek (and be entitled to) discovery of NCH's false marking as evidence of its deceptive intent with regard to the other Novartis cases. Second, given the intent of the relators (Mr. Simonian and the Foundation) to move forward *with only one case* against NCH (however that is accomplished, with leave of Court), the motion to dismiss based on a "prior pending case" should be dismissed as moot.

IV. Conclusion

For the foregoing reasons, the Relator respectfully requests that this Court deny the Novartis Defendants' Motion to Dismiss.

Respectfully submitted,

THOMAS A. SIMONIAN, as Relator

By /s Robert D. Cheifetz
One of his attorneys

Bruce S. Sperling
Robert D. Cheifetz
Sperling & Slater, P.C.
55 W. Monroe, Suite 3200
Chicago, Illinois 60603
(312) 641-3200

Joseph M. Vanek
Vanek, Vickers & Masini
111 S. Wacker Drive, Suite 4050
Chicago, Illinois 60606

Eugene M. Cummings
Eugene M. Cummings, P.C.
One North Wacker Drive, Suite 4130
Chicago, Illinois 60606